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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,588	01/14/2000	Leonard Presta	P1726R1	8570

7590 09/03/2002
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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	14

DATE MAILED: 09/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

483 588

Applicant(s)

PRESA

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/25/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-15, 23-30, 36-37 is/are pending in the application.
- ☐ Claim(s) _____ is/are withdrawn from consideration.
- Of the above claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☒ Claim(s) 1-15, 23-30, 36-37 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.
- ☐ Claim(s) _____

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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Claims pending are 1-15, 23-30 and 36-37.

Applicant's election without traverse of Group I (claims 1-15, 23-30 and 36-37) in Paper No. 13 is acknowledged.

Claims 14-15, which were listed with both Groups I and II in the restriction stated 9/25/01, will be examined for the embodiment of Group I -- i.e variants with increased binding to at least one Fc receptor.

Claims 10 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "lower hinge region" in claim 10 is a relative term which renders the claim indefinite. The term "lower hinge region" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification defines no bound (e.g. residue position) for the term "lower hinge".

Claim 14 must be amended to reflect the elected embodiment of group I.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 5-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Better et al (5,576,184).

Better et al show chimeric antibodies with better ADCC activity than the corresponding mouse antibodies. See col. 30, lines 47-60; col. 31, lines 11-23, col. 32, lines 37-47. Chimeric antibodies clearly meet the limits of claims 1-2 and 8-10.

It is proper to consider chimeric antibodies as anticipating, since they are obtained by altering parent polypeptides (mouse antibodies) at at least one amino acid residue in the Fc region. The examiner finds nothing in the term definitions in applicant's specification that renders this reading of the claim language unreasonable. Claims 5-6 are included, since applicant has disclosed (page 27) that Fc.gamma.RIII is critical for mediating ADCC.

Claim 36 is anticipated since the antibodies of Better et al were prepared in PBS, which is a pharmaceutical carrier. See col. 28, lines 62-67; col. 29, lines 19-24; col. 30, lines 22-28.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Better

et al.

Better et al have been noted supra for teaching chimeric antibodies having enhanced ADCC activity. They teach therapeutic uses (col.14, lines 1-24), for which provision in a pharmaceutical carrier that is sterilized was art conventional and hence obvious.

Claims 1-4,8-9, 14-15 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chappel et al (JBC, 268, 25124, 1993 -- ref. 127).

Chappel et al show mutated forms of human IgG1 and IgG2 antibodies which show increased binding to Fc.gamma. RI. See abstract and Table II. The altered residues shown therein are consistent with the limitations of dependent claims 3-4, 8-9 and 14-15. Claim 36 is rejected since the mutated IgGs were prepared in PBS (para. Spanning cols. 1-2 of p. 25125).

Claims 1-5 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarmay et al (Molec. Immunol., 29, 633, 1992 -- ref. 107).

Sarmay et al teach a mouse-human IgG2b chimeric antibody mutated at position 235, from Glu to Leu. This mutation provides an antibody having increased ADCC activity. See para spanning pp. 535-637 and Fig. 4.

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Claims 1-4, 8-10, 14-15, 23 27-28 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan et al WO 94/29351 -- ref. 6).

Morgan et al disclose (pp.16-17) a human IgG1 antibody having a K320A mutation . This antibody thus inherently has all the features of claims 1-4, 8-10, 14-15, 23 and 27-28. Note that position 320 was thus substituted by applicant (instant Table 2) and is recited in instant claims 14, 23, and 28. While Morgan et al do not show the instantly recited property of increased binding to Fc.gamma.RII, this property must have been inherent, because their antibody is structurally the same as applicant's antibody thus substituted at position 320.

Claim 36 is included because the antibodies of Morgan et al were diluted in PBS (p. 32).

Claims 1-6, 8-11, 14-15, 23-24, 26-30 and 36-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Idusogie et al (6,242,195).

Idusogie et al disclose (col. 38, lines 1-54) the existence of mutant forms N276A, K320A, K322A, P331A, K334A which were assessed for their ability to bind C1q and activate complement. These mutants correspond to various mutant forms listed in instant Table 2 (variants of parts 3 and 8). Note also listings in instant Table 6 (variants 21, 48, 49, 65 and 55 correspond to variants N276A, K320A, K322A, P331A and K334A of the reference, respectively).

While Idusogie et al do not disclose evaluation of the FcR binding affinity or of ADCC with respect to these mutants, these necessarily had the inherent properties shown by applicant in the instant disclosure (Tables 2 and 6) of having an increased binding affinity for at least one FcR.

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The fact that Idusogie et al did not recognize this inherent property does not detract from anticipation.

Dependent claims 2-4 clearly fall within the above noted teachings of the reference. Claim 5 is included because the K334A mutant would inherently show (instant Table 2) increased binding to Fc.gamma.RIII, which applicant has disclosed as being the critical FcR for mediating ADCC (Pg. 27). Claim 6 is thus also included. Claims 8-10 clearly fall within the above noted teachings since position 334 lies beyond the lower hinge region. Claim 11 is included because it recites position 334. Claims 14-15, 23-24 and 26-30 are included, since they encompass substitutions at positions taught by the reference and recite properties of such variants as shown in instant Tables 2 and 6. Compositions as recited in instant claims 36-37 are shown in the reference (col. 30, line 31-col. 31, line 11).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D. whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Thu. from 8:00 to 5:30. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Retyped 9/2/02, DAS, AW3.3-483588.fa

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 / 1644

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.